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Citation	Snowdon, Claire, Peter Brocklehurst, Robert Tasker, Martin Ward Platt, and Diana Elbourne. 2013. "Feeding back the results of trials to the families of participants who have died: methodological considerations from the bracelet study (bereavement and randomised controlled trials)." <i>Trials</i> 14 (Suppl 1): O32. doi:10.1186/1745-6215-14-S1-O32. http://dx.doi.org/10.1186/1745-6215-14-S1-O32 .
Published Version	doi:10.1186/1745-6215-14-S1-O32
Accessed	February 19, 2015 3:56:46 PM EST
Citable Link	http://nrs.harvard.edu/urn-3:HUL.InstRepos:12152924
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ORAL PRESENTATION

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Feeding back the results of trials to the families of participants who have died: methodological considerations from the bracelet study (bereavement and randomised controlled trials)

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From 2nd Clinical Trials Methodology Conference: Methodology Matters
Edinburgh, UK. 18-19 November 2013

Increasingly trial results are fed back to participants and their families, but there is little research about this process if the participant dies. This issue was explored in the BRACELET Study (Bereavement and Randomised Controlled Trials) (<http://www.bracelet-study.org.uk>). We conducted 30 interviews with 51 bereaved parents of babies who were entered into one of five neonatal intensive care trials, and 58 clinicians and/or trial team members.

Bereaved parents expressed a range of views but almost unanimously supported offering parents trial results. Results were important for information, but also as an acknowledgement of loss and contributions to research, as connections to their baby and for commemoration and consolation. Parents thought that feedback would help them feel that their baby was not forgotten but valued as an individual, conferring meaning to a short life.

Feedback is however not straightforward. Trials may take a long time to recruit, analyse and report results. Parental circumstances can change over time: those disinclined to consider receiving results at an earlier stage of bereavement may change their views; those initially interested may become less so. The capacity of a trial team to respond may also change: dedicated trial staff may no longer be in post, funds for feedback may be limited and parental addresses may no longer be current.

Further careful studies of feedback of results are needed in a variety of trial settings to understand how trial teams manage this situation, and to explore how

results are received and understood by both bereaved and non-bereaved families.

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Published: 29 November 2013

doi:10.1186/1745-6215-14-S1-O32

Cite this article as: Snowdon *et al.*: Feeding back the results of trials to the families of participants who have died: methodological considerations from the bracelet study (bereavement and randomised controlled trials). *Trials* 2013 **14**(Suppl 1):O32.

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